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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,439	11/04/2003	Christopher Burgess	1657/2022	5656

29932 7590 08/29/2006

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EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/700,439	BURGESS ET AL.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 4 Nov 2003.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-186. Claims 1-34, drawn to distinct nucleic acids or polypeptides corresponding to SEQ ID NO:1-186, classified in class 536, subclass 23.1 or class 530, subclass 300.

Once a group has been elected from those listed above, a further single subgroup must be elected from the Groups below.

A. Claims 1-5, drawn to method of detecting differential expression, classified in class 435, subclass 6.

B. Claims 6-7, drawn to method of detecting cancer, classified in class 435, subclass 6.

C. Claims 8-9, drawn to method of monitoring onset progression or regression of cancer, classified in class 435, subclass 6.

D. Claims 10-12, drawn to method of determining prognosis for cancer, classified in class 435, subclass 6.

E. Claims 13-14, drawn to method of determining the efficacy of a test compound for inhibiting cancer, classified in class 435, subclass 6.

F. Claims 15-16, drawn to method of determining the efficacy of a therapy for inhibiting cancer, classified in class 435, subclass 6.

G. Claims 17-18, drawn to method of selecting a composition for inhibiting cancer, classified in class 435, subclass 6.

H. Claim 19, drawn to method of inhibiting cancer in a subject, classified in class 435, subclass 6.

I. Claim 20, drawn to a polypeptide sequence selected from the group consisting of SEQ ID NO:94-186, classified in class 530, subclass 300.

J. Claims 21-23, drawn to an antibody that specifically binds a polypeptide sequence selected from the group consisting of SEQ ID NO:94-186, classified in class 424, subclass 130.1.

K. Claims 24-27, drawn to method of detecting a polypeptide, classified in class 435, subclass 7.1.

L. Claim 28, drawn to method of detecting cancer, classified in class 435, subclass 7.23.

M. Claim 29, drawn to method of monitoring onset progression or regression of cancer, classified in class 435, subclass 7.23.

N. Claim 30, drawn to method of determining prognosis for cancer, classified in class 435, subclass 7.23.

O. Claim 31, drawn to method of determining the efficacy of a test compound for inhibiting cancer, classified in class 435, subclass 7.23.

P. Claim 32, drawn to method of determining the efficacy of a therapy for inhibiting cancer, classified in class 435, subclass 7.23.

Q. Claim 33, drawn to method of selecting a composition for inhibiting cancer, classified in class 435, subclass 7.23.

R. Claim 34, drawn to method of inhibiting cancer in a subject, classified in class 435, subclass 7.23.

The inventions are independent or distinct, each from the other because:

Polynucleotides and Polypeptide Molecules

Inventions 1-186 are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

Applicants are reminded that nucleic acid sequences encoding different proteins, and the amino acid sequences they encode, are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleic acid and amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the proteins encoded by these sequences differ in structure and in function and in biological activity. Further, even where the nucleic acid changes have no effect on protein structure or function, these sequences themselves represent allelic variations which have different diagnostic and therapeutic implications. A restriction is applied to each Group. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequences (See MPEP 803.04).

Distinctions between Method Subgroups

The polypeptides of Subgroup I and the antibodies of Subgroup J are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, the polypeptide claims do not overlap the scope of the antibody claims and vice versa as evidenced by the distinct structures and functions of the claimed inventions. While both polypeptides and antibodies are structurally related by virtue of their contiguous sequence of amino acids, they are distinct structures based on their three-dimensional structures wherein proteins fold into a variety of structures and antibodies maintain a specific, Y-shape. Polypeptides are functionally distinct from antibodies because antibodies merely recognize a cognate peptide fragment of said

polypeptide and polypeptides affect a specific binding to ligand. Additionally, the polypeptides and antibodies are not obvious variants of each other based on the distinct structures and functions of each as noted above. Lastly, the polypeptides and antibodies have materially different functions as noted above. Thus, by virtue of the different structures and functions of the inventions of Subgroups I and J, these related inventions are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Moreover, the search required is distinct based on the distinct structures as noted above. Thus, to search the proteins with the antibodies would be unduly burdensome. Therefore, Subgroup I is properly restricted from Subgroup J as being distinct and unduly burdensome to be searched together.

Antibodies in Methods

Inventions J and K-R are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the various methods of K-R can use ligands other than the antibodies of Invention J.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, or divergent subject matter, or the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101; 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**
Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Response Requirement

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Multiple Inventors

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave Nguyen** can be reached on **571-272-0731**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long
Patent Examiner
Art Unit 1633

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER